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October 30, 1998

Office of Special Nutritionals
HFS-450 Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C St.SW
Washington DC 20204

Statement of Nutritional Support- ST. JOHN'S WORT EXTRACT
Pursuant to 21 CFR Part 101.93, American Specialty Health &
Wellness (ASHW) files the following Statement of Nutritional
Support for the Dietary Supplement marketed as: ST. JOHN'S WORT
EXTRACT

- 1) Name and Address of Distributor: ASHW 8989 Rio San Diego Dr. Ste. 250, San Diego CA 92108
- 2) Text of Nutritional Support Statement being Made: "St. John's Wort, also known as Hypericum, is used to support the immune system and emotional well-being."
- 3) Name of dietary ingredient(s): See Attached Product Label
- 4) Brand Name: ST. JOHN'S WORT EXTRACT
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Dr. Doug Metz, Vice President.

Yours truly,

Dr. Doug Metz

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Vice President

## St. John's Wort Extract

## **Description:**

St. John's Wort, also known as Hypericum, is used to support the immune system and emotional well being. The flowers of the plant contain a substance called hypericin and other compounds called flavonoids, which are the active ingredients of the plant.

These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Directions For Use: Take 1 capsule per day.

Storage: Keep lightly closed in a cool, dry place.

Caution/Warning: As with any supplement, herb or medication, do not provide it to a child without consulting a physician. Do not use for extended periods of time. Possible side effects of St. John's wort are elevated blood pressure, headache, stiff neck, nausea, and blistering after sun exposure. Do not use St. John's wort if you are pregnant or lactating.

Note: This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

DISTRIBUTED BY AMERICAN SPECIALTY HEALTH & WELLNESS\*\*
PO BOX 509010, SAN DIEGO, CA 92150-9040

## ST. JOHN'S WORT EXTRACT

**60 CAPSULES** 

Premium Products for Your Health & Wellness™

**Supplement Facts** 

Size: 1 Capsule - Servings Per Container: 60

Amount Per Serving: % Daily Yalve

St. John's wort extract (Hypericum perforatum bud & flowering lop, std 0.3% hypericines)

300mg

Other Ingredients: Gelatin, cellulose, calcium phosphate hydrous, stearic acid, magnesium stearate and silicon dioxide.

\*Daily Value not established.

St. John's Wort Extract is free of wheat, corn, soy, dairy, sucrose, starch, salt and yeast.